

## **REMARKS**

In the aforesaid final Office Action, the amendment filed 2/14/2007 was objected to under 35 USC 132(a) as introducing new matter, claims 26, 28-29, were rejected under 35 USC 102(b) as being anticipated by Wang et al. (US 5,556,383), and claims 30-33, 36 and 37 were rejected under 35 USC 103(a) as being unpatentable over Wang et al. alone. Claims 26 and 28-37 are pending.

The Examiner objected to the amendment of 2/14/2007 under 35 USC 132(a), stating, in part, that there is no disclosure in the specification about the outer diameter at the inflation pressure at the substantially ambient temperature as part of a catheter system, and that there is no way one can determine if “the inflated configuration outer diameter at the inflation pressure as part of a catheter system” is measured when the balloon is at the same ambient temperature as that of the balloon after the heat treatment process.

However, the Examiner’s attention is directed to paragraph [0032] disclosing that the radial shrinkage is measured by the % change in the outer diameter of the working length of an inflated balloon as part of a catheter system, versus as formed after the present process. The plain meaning of the above quoted passage of para. [0032] in the context of the application is that the inflated diameters are to be compared at otherwise the same inflation conditions (i.e., the conditions which produce the inflated outer diameter are the same, and would have produced the same inflated outer diameter in the absence of the radial shrinkage determined by the measurement). To read the quoted

passage of para. [0032] otherwise would not allow for the outer diameter of the working length of an inflated balloon as part of a catheter system to be “versus”, or in contrast to, the outer diameter of the working length of the inflated balloon as it was originally formed by the present process. Thus, the amendment to claim 26 is fully supported, and the percent radial shrinkage of the balloon clearly does not refer to a percent change in the balloon inflated diameter which is caused by a change in temperature (or inflation pressure), in contrast to statements by the Examiner in the rejection based on Wang et al.

As set forth in MPEP 2163.02, Applicant satisfies the written description requirement by conveying with reasonable clarity to those skilled in the art Applicant’s possession of the invention now claimed. The quoted passage of para. [0032] in the context of the specification, and specifically taken together with the disclosure at paragraphs [0008] and [0034] relating to cooling the balloon as formed by the present process to substantially ambient temperature while pressurized in the mold, does convey with reasonable clarity to those skilled in the art that at the time of filing applicant was in possession of the invention as now claimed.

Pursuant to MPEP 2163.04, the Examiner must present evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure (and in particular the quoted passage of para. [0032] taken together with paragraphs [0008] and [0034]) a description of the invention defined by the claims. Applicants have pointed out above where the limitations of claim 26 are supported, and the Examiner is required to comment on the substance of Applicants remarks pursuant to MPEP 2163.04 if the Examiner finds that the disclosure does not reasonably convey that the inventor had

possession of the subject matter of the amendment at the time of the filing of the application.

Applicant's disclosure is directed to significantly increasing the dimensional stability of the balloon which provides a balloon that is more predictable in use. The terminology "radial shrinkage" is explicitly defined in paragraph [0032] and would be understood to refer to the way in which inflating a blow-molded balloon at a given working pressure produces an inflated outer diameter (related to the mold used to blow-mold the balloon) which is greater than the inflated outer diameter that later results when the balloon is similarly inflated after being exposed to the treatments which cause the radial shrinkage and which are part of preparing the balloon as part of a finished catheter system ready for use. The "change" which quantifies the percent radial shrinkage of the balloon would thus be understood to refer to conditions which produce comparable inflated outer diameters (i.e., conditions which, apart from being before and after the balloon is exposed to treatments which cause the radial shrinkage, would have otherwise produced the same inflated outer diameter). Moreover, claim 26 requires that the balloon (heat set using a heating member applying heat simultaneously along the length of the balloon) has an inflated outer diameter radial shrinkage which is less than that of a balloon heat-set nonuniformly, which further defines the conditions for determining the shrinkage percentage in claim 26.

The Examiner rejected the claims based on Wang et al., stating that Wang (example 1 and table 1) discloses a polymeric balloon having a having radial shrinkage less than 6% and a length of about 2 cm.

However, Wang example 1 discloses a balloon having an inflated outer diameter which is equal to the inner diameter of the balloon mold/nominal outside diameters of the balloons at ambient temperature. Wang et al. explicitly discloses at col. 6, lines 30-36 that a 3.0 mm size mold was used to produce a 3.0 mm balloon. Additionally, although Wang discloses the growth of the balloon as the inflation pressure is increased to pressures above the inflation pressure used to inflate the blow-molded balloon, in contrast, Applicant's claim 26 requires dimensional stability at the inflation pressure used to inflate the blow-molded balloon to its inflated configuration, as discussed above. Therefore, although Wang does disclose non-compliant balloons which have a limited, 2-7%, diameter increase as the balloons are pressurized above e.g., 6 atm, Wang is comparing the inflated outer diameter at the nominal inflation pressure of the balloon to an inflated outer diameter at a different, higher inflation pressure, such that Wang does not disclose or suggest a balloon having a radial shrinkage of less than 10% but greater than 0% as required by Applicant's claim 26.

Moreover, Applicant's claim 26 requires that the balloon (heat set using a heating member applying heat simultaneously along the length of the balloon) has an inflated outer diameter radial shrinkage which is less than that of a balloon heat-set nonuniformly, which would not appear to be the case for an inflated outer diameter change envisioned by the Examiner as being due merely to an increasing inflation pressure while inflating a blow-molded balloon in Wang.

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Please charge or credit Deposit Account No. 06-2425 for any additional fees in connection with this preliminary amendment.

Respectfully submitted,

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